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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,388	02/05/2004	Horst Georg Zerbe	2004-0189	3058

7590 05/02/2007
Michael R. Davis
WENDEROTH, LIND & PONACK
Suite 800
2033 "K" Street N.W.
Washington, DC 20006-1021

EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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05/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/771,388

Applicant(s)

ZERBE ET AL.

Examiner

Lezah W. Roberts

Art Unit

1614

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 April 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

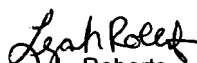
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): 35 USC § 101/35 USC § 112 and 35 USC § 112 – New Matter.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 10-40.
Claim(s) withdrawn from consideration: 41-51.


AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____


Leah W. Roberts
Patent Exmr.
AU 1614


F. Krass
Primary Exmr.
AU 1614

Continuation of 3. NOTE: The amendments change the scope of the claims by requiring two or more polymers in the films as opposed to one polymer. This requires a further search to determine if this limitation would be obvious to one of ordinary skill in the art.

Continuation of 11. does NOT place the application in condition for allowance because:

The reference DE 196 15 820 has been withdrawn.

"Mucoadhesive" is claimed broadly and all that is required to meet that broad limitation is some degree of adhesion. The prior art film would become sticky upon hydration and thus "mucoadhere" to at least some degree. Moreover, in regards to transmucosal delivery, this intended use carries no weight when determining the patentability of the instant claims. The type of active agents are not specified by the instant claims such that transmucosal delivery MUST occur. (Applicant could perhaps specify that the pharmaceutically active agent be able to cross the mucosa upon administration (without introducing "New Matter") in order for the claims to be in possible condition for allowance).

Accordingly, all rejections are maintained in view of Schmidt.

In regards to Keith et al., Examiner withdraws the statement "discloses polyvinylpyrrolidone acts as an odor masking substance". Nevertheless, it would still have been obvious to use a flavorant in order to provide improved taste.

In regards to Story et al., Applicant is using a piecemeal analysis. The reference discloses the benefits of using one or more surfactants as well as surfactants used to deliver pharmaceutically active agent. The benefits include improved solubility for the active agent when a mixture of surfactants is used (col. 8, lines 9-11). Therefore it would have been obvious to one of ordinary skill in the art to have used a mixture of surfactants to ensure the active agent was dissolved when making the films.